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RESULTS: All eight patients favorably appraised the format of the revised instrument. Patients reported that the SFB-SUI generally provided an accurate assessment of their condition and associated bothersomeness. Changes resulting from the interviews included the addition of one new item, the deletion of two items, and modification of both response scales. The final version of the SFB-SUI now consists of 8 items.

CONCLUSION: Preliminary investigation of the SFB-SUI indicates that it is a two-subscale measure for symptom frequency and bothersomeness specific to stress urinary incontinence. Psychometric evaluation will be performed in subsequent clinical trials being conducted in stress urinary incontinence patients.

PUK8

VALIDATION OF THE PERCEPTION OF BLADDER CONDITION MEASURE IN OVERACTIVE BLADDER

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OBJECTIVES: Overactive bladder (OAB) is characterized by bothersome symptoms of urinary frequency and urgency that occur with or without urge incontinence, and it has been shown to have significant impact on health-related quality of life (HRQL). Since OAB is defined by symptoms, the evaluation of treatment effectiveness should be based upon patient perception. The purpose of this study was to assess the validity and responsiveness of a global patient-report measure—the Perception of Bladder Condition (PBC) in Overactive Bladder.

METHODS: OAB patients were treated with Tolterodine Extended Release 4 mg/day for 12 weeks. Patient evaluations, which included the PBC, OAB-q (measure of symptom bother and HRQL), and micturition variables (3-day diaries: frequency, incontinence, urgency), were conducted at baseline, 4 weeks, and 12 weeks. The PBC is a single item that assesses current urinary problems on a 6-point scale. PBC scores were evaluated with other measures of treatment efficacy using t-tests and ANOVAs for all assessment periods.

RESULTS: 865 patients completed the study (mean age = 61 years; 73% female; 89% Caucasian). Higher severity PBC responses were significantly associated with greater symptom bother and lower HRQL at each assessment period ($p < 0.05$). Associations between PBC and micturition variables followed similar patterns. Compared with patients who did not report improvement on the PBC, patients who improved demonstrated significantly greater improvement from baseline to week 12 on all OAB-q scales ($p < 0.0001$), micturition frequency ($p < 0.0001$), incontinence episodes ($p < 0.002$), and urgency episodes ($p < 0.005$). Patients reporting major improvement on the PBC (>2 response options) consistently demonstrated significantly greater improvement on other

efficacy measures compared to patients reporting minor improvement.

CONCLUSIONS: The Perception of Bladder Condition demonstrated good construct validity and responsiveness among patients receiving Tolterodine Extended Release 4 mg/day for Overactive Bladder. It appears to be a useful tool for evaluating patients' global impressions of bladder condition in clinical trials of OAB treatments.

PUK9

VALIDATION OF THE URGENCY PERCEPTION SCALE

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OBJECTIVES: Urinary urgency is a central symptom of overactive bladder (OAB) and is particularly bothersome due to its unpredictable nature and consequent impact on daily living. There are no objective clinical measures of urgency and there is a need for a validated, standardized instrument. The purpose of this study was to ascertain the validity and responsiveness of the Urgency Perception Scale (UPS) as an indicator of perceived urinary urgency.

METHODS: Content validity was assessed by interviews with OAB patients and clinical experts. Secondary analyses of clinical and patient outcome data gathered from three separate clinical studies of tolterodine extended release were performed to evaluate the psychometric properties of the UPS. Construct validity was assessed by correlations between the UPS and micturition diaries and other patient-reported outcomes including perception of bladder condition, perception of treatment benefit, SF-36, King's Health Questionnaire, Overactive Bladder Questionnaire, and Overall Treatment Effect scale. Analysis of variance was used to assess the UPS's construct validity and responsiveness.

RESULTS: The UPS was considered an appropriate and reasonable assessment of urinary urgency by patients ($n = 16$) and clinicians ($n = 7$). Data from a total of 2,686 patients from three clinical studies were analyzed; the baseline clinical and demographic characteristics were similar among the three patient samples. Correlations with patient outcomes and clinical variables were small to moderate (0.09 to 0.46, $p < 0.01$) with higher correlations associated with disease-specific patient outcome measures. Responsiveness was supported by improvements in the UPS score at the end of treatment that were consistently associated with significant ($p < 0.05$) reductions in micturitions associated with urgency, incontinence episodes, and pad use.

CONCLUSION: The UPS is a conceptually valid scale with evidence of construct validity and responsiveness from three clinical studies. This work demonstrates that perceived urinary urgency and changes in urinary urgency can be assessed.